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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,361	06/20/2003	Jean-Marie Andrieu	1187-R-02	7112

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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,361	ANDRIEU ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 4-5, 11-12, 14-18, 20, and 25, drawn to a composition and a vaccine comprising an antigen-presenting cell pulsed with inactivated HIV virus, classified in class 424, subclass 93.6.

II. Claims 1, 3-5, 11, and 13, drawn to a composition comprising an antigen presenting cell pulsed with inactivated SIV virus, classified in class 435, subclass 235.1.

III. Claims 1, 4-12, and 30, drawn to a composition comprising an antigen-presenting cell pulsed with inactivated HIV virus and a protease inhibitor, classified in class 424, subclass 94.1.

IV. Claims 1, 4-12, and 30, drawn to a composition comprising an antigen-presenting cell pulsed with inactivated SIV virus and a protease inhibitor, classified in class 424, subclass 94.1.

V. Claims 21, drawn to a method of controlling an immunodeficiency viral load, classified in class 435, subclass 243.

VI. Claims 22, drawn to a method of inducing an immune response in a mammal, classified in class 424, subclass 208.4.

VII. Claim 23, drawn to a method of inducing protective antibodies to HIV, classified in class 436, subclass 543.

VIII. Claim 24, drawn to a method of inducing protective antibodies to SIV, classified in class 436, subclass 543.

IX. Claim 26, drawn to a method of inducing an anti-HIV immune response, classified in class 424, subclass 208.1.

X. Claim 27, in part, drawn to a method of inducing production of anti-HIV immunity comprising the administration of a purified HIV virus, classified in class 424, subclass 208.1.

XI. Claim 27-28, claim 27 in part, drawn to a method of inducing production of anti-HIV immunity comprising the administration of a purified HIV virus and a virus infected host cell, classified in class 424, subclass 208.1.

XII. Claim 27-28, claim 27 in part, drawn to a method of inducing production of anti-HIV immunity comprising the administration of a virus infected host cell, classified in class 424, subclass 208.1.

XIII. Claim 29, drawn to a method of treating HIV infection with the administration of antibodies, classified in class 424, subclass 207.1.

XIV. Claim 31-32, drawn to a method of inducing production of anti-HIV immunity comprising the administration of dendritic cell pulsed with HIV virus and a protease inhibitor, classified in class 424, subclass 208.1.

XV. Claim 19, drawn to a method of eradicating HIV, classified in class 435, subclass 373.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Groups I-IV and V-XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. The product of Groups I-IV can be used to any of the methods recited in Groups V-XIV, such as to control viral load, induce immune response, induce protective antibodies, and induce an anti-HIV immune response.

3. Inventions of Groups I-IV unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects due to the different materials used in each composition. The composition of Group I comprises an antigen-presenting cell pulsed with inactivated HIV virus, the composition of Group II comprises an antigen-presenting cell pulsed with inactivated SIV virus, the composition of Group III comprises an antigen-presenting cell pulsed with inactivated HIV virus and a protease inhibitor, and the composition of Group IV comprises an antigen-presenting cell pulsed with inactivated SIV virus and a protease inhibitor.

4. Inventions of Groups V-XIV unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects due to the materials used, steps, and population with which the method targets. The invention of Group V is directed to inducing an immune response in a mammal, the invention of Group VI is directed to controlling an immunodeficiency viral load, the invention of Group VII is directed to inducing protective antibodies to HIV, the invention of Group VIII is directed to inducing protective antibodies to SIV, the invention of Group IX is directed to inducing an anti-HIV immune response, the invention of Group X-XII, and XIV is directed to inducing production of anti-HIV immunity, and the invention of Group XIII is directed to treating HIV infection.

5. Inventions of Groups X-XII, and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different function and/or effects. The inventions of Group X-XII, and XIV differ in the materials use, thus, yielding different effects and/or functions. The materials used in Group X is purified HIV virus, the materials used in Group XI is a purified HIV virus and a virus infected host cell, the materials used in Group XII is virus infected host cell, and the materials used in Group XIV is dendritic cell pulsed with HIV virus and a protease inhibitor.

6. Inventions of Group XV and Groups V-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions differ in modes of operation, functions, and effects. The invention of Group XV differ from that of Groups V-XIV in method steps. The method of Group XV requires culturing, expanding, and exposing T cells, whereas the methods of Groups V-XIV requires the administration of a compound.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-XV, restriction for examination purposes as indicated is proper

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (703) 305-4452. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0169.

E. Le

James C. Housel
JAMES HOUSEL 12/15/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600